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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,695	01/16/2004	Gerianne Tringali DiPiano	FEM 105	8448

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EXAMINER	
VU, QUYNH-NHU HOANG	
ART UNIT	**PAPER NUMBER**
3763	
MAIL DATE	**DELIVERY MODE**
11/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,695	DIPIANO ET AL.	
	Examiner	Art Unit	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is supplemental to the Previous Action mailed out 10/17/08

Response to Amendment

Amendment filed on 8/13/08 has been entered.

Claims 1-6, 8-11 are present for examination.

Claim 7 is cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations of claims 1 and 6 state that: "...the medication chamber is designed to contain up to 1 mL of a pharmaceutical composition..." are not consistency with the Specification.

The limitations above can be understood as "the medication chamber is designed to contain the volume less than or equal to 1mL. While, the Specification on page 4, lines 1-2 states that the medication chamber is large enough to contain a small volume of a pharmaceutical composition, which is less than 1 mL (not equal to 1mL).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-6 and 8-11 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jones (US 2,847,011).

. Jones discloses a vaginal or rectal applicator comprising: an applicator barrel 11 comprises a medication chamber 15 at the proximal end of the applicator; wherein the medication chamber has a smaller diameter than the diameter of the applicator barrel and wherein the medication chamber is filled with the desired volume of a medicament (col. 2, lines 63-64), therefore, it can be designed to contain up to 1mL of a pharmaceutical; the pharmaceutical composition is in form selected from the group consisting of powder, gel, cream or lotion (col. 1, lines 15-20); and wherein the proximal end of the applicator contains an opening suitable for filling the medication chamber with the pharmaceutical composition and dispensing the pharmaceutical composition from the medication chamber; and wherein the applicator barrel comprises a barrier 21 or 14 proximal to the opening; a plunger 10; a plunger tip 16; an applicator cap 18 is removable from the proximal end of the applicator barrel.

As noted that, the applicator of Jones suitable for insertion into the vagina (col. 1, lines 15-25). Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., "...suitable for insertion into the vagina or rectum and suitable for preventing penetration of the vaginal wall, cervix or rectum", a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

Regarding to claim 4, since the applicator cap 18 is covered the tip 19, therefore, the cap 18 not only performing protection but also closed and sealed tip 19. Therefore, the cap 18 forms air-tight seal with the applicator barrel. Not only that, it is well-known in the art to provide the cap forms air-tight seal with the applicator barrel. For example: if the cap and tip of applicator has thread and corporate close with each other or provide a metal foil sealed tip of barrel and formed air-tight seal.

Regarding claims 5, the plunger tip 21 forms an air-tight seal with the applicator barrel (col. 4, lines 1-10).

Regarding claims 6, 8-11, they encompass the same scope of the invention as to that of claims 1-5 except they are drafted in method format instead of apparatus format. These steps must be performed in order to obtain the device. Therefore, the method of performing or transvaginal or transrectal drug delivery would be inherent to the shown structure of the device. For example: before using condition and after the barrel 11 is filled in the medicament, the barrel 11 is sealed with the plug 13 or closed with the cap 18 (or placing a cap on the proximal end of applicator barrel) for protection (Figs. 1-2, 4). And right before dispensing in to patient, the cap 18 is removed to be ready insert into a patient's vagina or rectum.

Claim 2 is rejected under 35 U.S.C. 103(a) as obvious over Jones.

Regarding claim 2, Jones discloses the invention substantially as claimed. Jones does not disclose the applicator further comprises a flange. However, it is well-known in the medical art or a container art to provide an applicator with the flange for the user manually handle easily.

Response to Arguments

Applicant's arguments with respect to claims 1-6 and 8-11 have been considered but are moot in view of the new ground(s) of rejection.

1. Applicant argues that Jones discloses an applicator that is not suitable for insertion into the vagina or rectum.

In response, Jones clearly disclose that this applicator suitable for insertion into the vagina (col. 1, lines 15-20). Furthermore, the limitation "for insertion into the vagina or rectum and suitable for preventing penetration of the vaginal wall, cervix or rectum" is functional limitation, as discussed above.

2. Applicant argues that Jones does not provide dimensions for the application.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Jones does not provide dimensions for the application) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

3. Applicant argues that Jones does not disclose the volume of medicament that the applicator can contain.

In response, Jones clearly discloses that the container 17 is filled with the desired volume of a medicament (col. 2, lines 64-65). Therefore, one skill in the art would be recognized that the applicator of Jones can contain with volume of 1 ml as desired and intended use.

4. Applicant argues that Jones does not disclose breech filling the applicator.

In response, the applicator of Jones is filled with medicament 15 or 17. Therefore, it is inherently to include the step of breech filling the applicator. Without the step of breech filling the applicator, the container 15 or 17 would be empty.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763